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EXAMINER	
STITZEL, DAVID PAUL	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,278	KESSLER ET AL.	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/7/02; 3/7/02;* 7/12/02; 1/30/03; 11/12/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: 5/9/05

5-06

OFFICIAL ACTION

Acknowledgment of Receipt

Receipt of the Applicant's Response, to the Official Action dated July 14, 2004, Declaration under 37 C.F.R. § 1.132 and Request for Continued Examination (RCE), which were filed on November 12, 2004, is acknowledged.

Status of Claims

Claims 1-9 were canceled, and claims 10-20 were added, by an amendment filed on March 25, 2004. In addition, claims 10-11 and 16-17 were amended, and claims 21-24 were added, by an amendment filed on November 12, 2004. As a result, claims 10-24 are currently pending and therefore examined herein on the merits for patentability.

Specification Objection

The disclosure of the specification is objected to because of the following informality: claim 21 contains subject matter that was not described in the disclosure of the specification as originally filed. More specifically, claim 21 is directed to a cosmetic and/or pharmaceutical preparation comprising bioactive glass particles, wherein "no *organic* chemical preservative compounds are present." Emphasis added. However, the specification on the other hand states that although "such preparations can be preserved with bioactive glass ... without it being necessary to add ... chemical preservatives ... it may be desirable to add the preservative of the invention to preparations ... with a *common* preservative so as to achieve a synergistic effect." Emphasis added. See page 5 of the specification. Although *common* preservatives, which exhibit bactericidal characteristics and are suitable for the treatment of skin, are known in the art to include not only *inorganic* metal cations, but also *organic* topical antibiotics, there is no written support in the specification as originally filed to specifically exclude "*organic*" chemical preservatives, per se, from the cosmetic

preparation. More particularly, it is commonly known in the art that *inorganic* metal cations (at low concentrations), such as Ag^{+}, Cu^{2+}, Cu^{+} and Zn^{2+}, as well as *organic* topical antibiotics, such as neomycin and polymyxin B, exhibit bactericidal characteristics and are suitable for the treatment of skin. However, there is no written language in the instant specification as originally filed that provides support for the language in claim 21, which recites in part that there are in fact no "*organic*" chemical preservatives present within the claimed invention. The lack of written support in the specification as originally filed for the language recited in claim 21 may be rectified by either amending the specification to include said language or canceling said language from claim 21 altogether. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112, which forms the basis of the claim rejections as set forth under this particular section of the Official Action:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More specifically, claims 13 and 19 both recite in relevant part that the bioactive glass particles "do not contain or release at least one *toxic* metal cation." Emphasis added. Based on the language of claims 13 and 19, it appears as though the bioactive glass particles either contain absolutely no toxic metal cations, with no *de minimis* exception, or alternatively said particles do in fact contain and release at least one "toxic" metal cation, but do so at concentrations that are not considered to be "toxic" when applied to the skin. That is, otherwise "toxic" metal cations are contained and released from said particles in non-toxic amounts when applied to the skin of a specific organism. In an effort to seek clarity for the aforementioned

vague and indefinite claims, reference was made to the specification, which states in relevant part that "the soluble bioactive glass does not contain or release toxic metal cations such as Ag^{+}, Cu^{2+}, Cu^{+} and/or Zn^{2+}, etc. in *toxic concentrations*. To achieve synergistic effects, however, it may in some cases be desirable to add also a *biocidal glass that does release toxic cations*." Emphasis added. See page 4 of the specification. Based on the aforementioned supporting disclosure, it appears that the claim interpretation as set forth hereinabove (i.e., that the bioactive glass particles may in fact contain and release at least one "toxic" metal cation, but must do so at concentrations that are considered to be non-toxic when applied to the skin of a specific organism, presumably human) is appropriate when said claims are given their broadest reasonable interpretation in light of the specification. See In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997).

Provisional Nonstatutory Double Patenting Claim Rejections With Secondary References

A nonstatutory double patenting rejection of the "obviousness-type" is based on a judicially created doctrine grounded in public policy (a policy reflected in 35 U.S.C. § 101) so as to prevent not only the unjustified or improper timewise extension of the "right to exclude" granted by a patent, but also possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re White*, 405 F.2d 904, 160 USPQ 417 (CCPA 1969); *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968); and *In re Sarett*, 327 F.2d 1005, 140 USPQ 474 (CCPA 1964).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned or assigned with this application. See 37 CFR

1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. See MPEP § 804. However, this does not mean that one is absolutely precluded from all use of the patent disclosure. See MPEP § 804. For example, the specification can always be used as a dictionary to learn the meaning of a term in the patent claim. *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Furthermore, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-442, 164 USPQ 619, 622 (CCPA 1970). The court in *Vogel* stated that one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court in *Vogel* also pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. § 103, since only the disclosure of the invention claimed in the patent may be examined."

1. Claims 10-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-18, 64-68 and 70 of copending U.S. Patent Application, Serial Number 09/818,466 (the "Lee et al. '466 patent application"), which was filed by at least one common inventor, namely Sean Lee and Susanna Kessler, on March 27, 2001, and published as a pre-grant publication (U.S. 2002/0086039) on July 4, 2002. ***The following claims analysis chart sets forth not only the claim limitations (which are drawn to a species) present in the instant application, but also the***

conflicting claims (which are drawn to a genus) and those corresponding portions of the specification within the disclosure of the Lee et al. '466 patent application that provide support for the conflicting claims by means of guidance as to what particular species fall within the scope of the claimed genus.

Method of Preserving a Perishable Cosmetic Preparation

10/030,278; Kessler et al.; Filed 4/9/02		09/818,466; Lee et al.; Filed 3/27/01		
Claim	**Limitation**	**Claims**	**Paragraph**	**Lines**
10	a method of preserving a perishable cosmetic preparation	14-18	0005	1-4
	adding an effective amount of bioactive glass particles to said	64-68	0006	1-6
	preparation to impart bactericidal properties to said preparation	70	0013	1
	bioactive glass particles having a diameter ≤ 5 um		0014	8-14
	bioactive glass particles ≤ 7 % by weight of said preparation		0017	2-8, 12-17
			0018	1-2, 4-8
			0020	6-11
			0038	1-3
			0039	1
			0041	1-9
			0042	1-5
			0043	1-6
			0044	1-15
			0045	1-8
			0046	1-12
			0074	1-4
			0077	1
			0078	1-22
			0127	1
			0128	1-6
			0129	1-3
			0232	1-2
			0237	1-4
			0241	1-4
			0242	1-2
11	bioactive glass particles from 0.1 to 5 % by weight	14-18	0046	1-12
		64-68		
		70		
12	bioactive glass particles having a diameter ≤ 2 um	14-18	0014	8-14
	bioactive glass particles ≤ 3 % by weight of said preparation	64-68	0018	1-2, 4-8
		70	0044	1-15
			0046	1-12
			0241	1-4

13	bioactive glass particles contain at least 2 % by weight of P2O5 bioactive glass particles do not contain or release at least one toxic metal cation	14-18 64-68 70	0012 0013 0047 0239 0240	1-7 1-5 1-6 1-15 1-7
14	at least one toxic metal cation is selected from the group consisting of Ag+, Cu2+, Cu+, and Zn2+	14-18 64-68 70	0012	1-7
15	bioactive glass particles contains SiO2 40-60 % by weight CaO 10-30 % by weight Na2O 10-35% by weight P2O5 2-8 % by weight CaF2 0-25 % by weight B2O3 0-10 % by weight K2O 0-8 % by weight MgO 0-5 % by weight	14-18 64-68 70	0013 0047 0239 0240	1-5 1-6 1-15 1-7

2. Claims 16-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 59-63, 69, 92-93 and 122-123 of copending U.S. Patent Application, Serial Number 09/818,466 (the "Lee et al. '466 patent application"), which was filed by at least one common inventor, namely Sean Lee and Susanna Kessler, on March 27, 2001, and published as a pre-grant publication (PG-Pub U.S. 2002/0086039) on July 4, 2002. ***The following claims analysis chart sets forth not only the claim limitations (which are drawn to a species) present in the instant application, but also the conflicting claims (which are drawn to a genus) and those corresponding portions of the specification within the disclosure of the Lee et al. '466 patent application that provide support for the conflicting claims by means of guidance as to what particular species fall within the scope of the claimed genus.***

Bactericidal Cosmetic Preparation

10/030,278; Kessler et al.; Filed 4/9/02		09/818,466; Lee et al.; Filed 3/27/01		
Claim	**Limitation**	**Claims**	**Paragraph**	**Lines**
16	a bactericidal cosmetic preparation	1-5	0014	8-14
	bioactive glass particles having a diameter ≤ 400 um	59-63	0015	1-4
	bioactive glass particles ≤ 10 % by weight of said preparation	69	0018	1-2, 4-8
	wherein said bioactive glass particles are present in an amount	92-93	0044	1-15
	sufficient to impart bactericidal properties to said preparation	122-123	0046	1-12
	wherein said bioactive glass particles have a refractive index sufficiently		0241	1-4
	close to that of a liquid carrier so that said bioactive glass particles			
	are substantially tranparent to a consumer thereby not effectuating			
	the appearance of said bactericidal cosmetic preparation			
17	bioactive glass particles having a diameter ≤ 10 um	1-5	0014	8-14
	bioactive glass particles having a diameter ≤ 5 um	59-63	0015	1-4
		69	0018	1-2, 4-8
		92-93	0044	1-15
		122-123	0241	1-4
18	bioactive glass particles contain at least 2 % by weight of P2O5	1-5	0013	1-5
		59-63	0047	1-6
		69	0239	1-15
		92-93	0240	1-7
		122-123		
19	bioactive glass particles do not contain or release at least one	1-5	0012	1-7
	toxic metal cation	59-63		
		69		
		92-93		
		122-123		
20	bioactive glass particles contains	1-5	0013	1-5
	SiO2 40-60 % by weight	59-63	0047	1-6
	CaO 10-30 % by weight	69	0239	1-15
	Na2O 10-35% by weight	92-93	0240	1-7
	P2O5 2-8 % by weight	122-123		
	CaF2 0-25 % by weight			
	B2O3 0-10 % by weight			
	K2O 0-8 % by weight			
	MgO 0-5 % by weight			
21	a bactericidal cosmetic preparation for contacting skin	1-5	0014	8-14
	bioactive glass particles ≤ 7 % by weight of said preparation	59-63	0018	1-2, 4-8
	wherein said bioactive glass particles are present in an amount	69	0044	1-15
	sufficient to impart bactericidal properties to said preparation	92-93	0046	1-12
	bioactive glass particles having a diameter ≤ 5 um	122-123	0241	1-4

22	bioactive glass particles having a diameter ≤ 2 um bioactive glass particles ≤ 5 % by weight of said preparation	1-5 59-63 69 92-93 122-123	0014 0018 0044 0046 0241	8-14 1-2, 4-8 1-15 1-12 1-4
23	bioactive glass particles ≤ 3 % by weight of said preparation	1-5 59-63 69 92-93 122-123	0046	1-12
24	cosmetic skin cream, lotion, make-up and lipstick	1-5 59-63 69 92-93 122-123	0078 0127 0128	1-22 1 1-6

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102, which forms the basis of the anticipation rejections as set forth under this particular section of the Official Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-14 and 21-24 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by U.S. Patent Number 5,290,544, which issued to Shimono et al. on March 1, 1994 (hereinafter the "Shimono et al. '544 patent").

Claims 10-12 are collectively directed to a method of preserving a perishable cosmetic preparation comprising the step of adding an effective amount of bioactive glass particles to said preparation to impart bactericidal properties to said preparation; wherein said bioactive glass particles are present in an amount of: less than or equal to 7 % by weight of said preparation (claim 10); from 0.1 to 5 % by weight of said

preparation (claim 11); and less than or equal to 3 % by weight of said preparation (claim 12); wherein said bioactive glass particles have a diameter of: less than or equal to 5 μm (claim 10); and less than or equal to 2 μm (claim 12). Similarly, the Shimono et al. '544 patent also discloses a method of preserving a perishable cosmetic preparation comprising the step of adding an effective amount of bioactive glass particles to said preparation to impart bactericidal properties to said preparation; wherein said bioactive glass particles are present in an amount of: less than or equal to 2.5 % by weight of said preparation; and from 0.5 to 2.5 % by weight of said preparation (column 1, lines 11-14 and 38-41; column 3, line 36; column 4, line 18; column 5, line 33; column 6, line 17; and column 7, line 9); wherein said bioactive glass particles have a diameter of less than or equal to 5 μm (abstract; column 2, lines 45-61; column 6, line 33; and claim 1).

Claims 13 and 14 are collectively directed to a method according to claim 10, wherein said bioactive glass particles contain diphosphorous pentoxide (P_2O_5) in an amount greater than or equal to 2 % by weight of said bioactive glass particles, and said bioactive glass particles do not contain or release at least one toxic metal cation, wherein said at least one toxic metal cation is selected from the group consisting of Ag^+, Cu^{2+}, Cu^+ and Zn^{2+}. Similarly, the Shimono et al. '544 patent also discloses a method of preserving a perishable cosmetic preparation, wherein bioactive glass particles contain diphosphorous pentoxide (P_2O_5) in an amount of 50 mole % of said bioactive glass particles (column 4, line 27; column 6, line 28; and column 7, line 21), and said bioactive glass particles do not contain or release at least one toxic metal cation selected from the group consisting of Ag^+, Cu^{2+}, Cu^+ and Zn^{2+}, in toxic concentrations when applied directly to the epithelial tissue of the skin (abstract; column 1, lines 6-10 and 46-53; column 2, lines 3-44; column 3, lines 3-11 and 36; column 4, line 18; column 5, line 33; column 6, line 17; column 7, line 9; and claim 1).

Claims 21-23 are collectively directed to a bactericidal cosmetic preparation comprising an effective amount of bioactive glass particles so as to impart bactericidal properties to said preparation; wherein said

bioactive glass particles are present in an amount of: less than or equal to 7 % by weight of said preparation (claim 21); less than or equal to 5 % by weight of said preparation (claim 22); and less than or equal to 3 % by weight of said preparation (claim 23); wherein said bioactive glass particles have a diameter of: less than or equal to 5 μm (claim 21); and less than or equal to 2 μm (claim 22). Similarly, the Shimono et al. '544 patent also discloses a bactericidal cosmetic preparation comprising an effective amount of bioactive glass particles so as to impart bactericidal properties to said preparation; wherein said bioactive glass particles are present in an amount of less than or equal to 2.5 % by weight of said preparation (column 1, lines 11-14 and 38-41; column 3, line 36; column 4, line 18; column 5, line 33; column 6, line 17; and column 7, line 9); wherein said bioactive glass particles have a diameter of less than or equal to 5 μm (abstract; column 2, lines 45-61; column 6, line 33; and claim 1).

Claim 24 is directed to a preparation according to claim 21, wherein said preparation consists of cosmetic skin cream, lotion, make-up and lipstick. Similarly, the Shimono et al. '544 patent also discloses a bactericidal cosmetic preparation, wherein said preparation comprises cosmetic skin lotion (skin cream is a species within the genus of skin lotion), make-up (i.e., foundation and eye shadow) and lipstick (column 2, lines 45-55 and 62-64; and claim 1).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15 and 20 are rejected under 35 U.S.C. § 103(a) as being obvious in light of the combined teachings of the Shimono et al. '544 patent and International Patent Application Publication Number WO 98/11853, which was filed by Greenspan and published on March 26, 1998 (hereinafter the "Greenspan '853 application").

Claims 15 and 20 are collectively directed to a method and composition, respectively, for preserving a perishable cosmetic preparation with an effective amount of bioactive glass particles added to said preparation so as to impart bactericidal properties to said preparation, wherein said bioactive glass particles contain the following inorganic compounds in the specified % by weight of said bioactive glass particles: 40-60 wt. % of SiO_2; 10-30 wt. % of CaO; 10-35 wt. % of Na_2O; 2-8 wt. % of P_2O_5; 0-25 wt. % of CaF_2; 0-10 wt. % of B_2O_3; 0-8 wt. % of K_2O; and 0-5 wt. % of MgO. Similarly, the Shimono et al. '544 patent also teaches a method and composition for preserving a perishable cosmetic preparation with an effective amount of bioactive glass particles added to said preparation so to impart bactericidal properties to said preparation. Although the bioactive glass particles, as taught in the Shimono et al. '544 patent, contain an overwhelming majority of the aforementioned inorganic compounds and in similar amounts with respect to said bioactive glass particles, CaF_2 is notably absent and the disclosed amounts of said inorganic compounds, although similar in nature, are not always overlapping in numerical value (column 3, lines 41-42; column 4, lines 26-27; column 6, lines 27-28; and column 7, lines 20-21). On the other hand, the Greenspan '853 application teaches a method and composition for protecting skin wounds from infection with an effective amount of a bactericidal bioactive glass composition comprising bioactive glass particles (page 1, lines 3 and 4 of paragraph 1; page 3, lines 1-3 of paragraph 2; page 9, lines 1-7 of paragraph 1; page 10 in its entirety; page 11, lines 1 and 2 of paragraph 3; page 12, lines 1-13 of paragraph 3; and claims 1-2 and 16) having diameters of less than or equal to 90 μm (page 11, lines 1-3 of paragraph 1; and claims 3-5) and one or more common

topical antibiotics, such as neomycin and polymyxin B (page 11, lines 1-7 of paragraph 2; and claims 6, 9 and 14). Although the Greenspan '853 application teaches bioactive glass particles containing the exact same inorganic compounds in the exact same % by weight as those recited in claim 15 (namely 40-60 wt. % of SiO_2; 10-30 wt. % of CaO; 10-35 wt. % of Na_2O; 2-8 wt. % of P_2O_5; 0-25 wt. % of CaF_2; 0-10 wt. % of B_2O_3; 0-8 wt. % of K_2O; and 0-5 wt. % of MgO), the Greenspan '853 application fails to specifically teach incorporating said bioactive glass particles, either alone or in combination with one or more common topical antibiotics, into a cosmetic preparation so as to impart bactericidal protection to said preparation. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the bactericidal bioactive glass particles or composition, as taught by the Greenspan '853 application, into a perishable cosmetic preparation, as taught by the Shimono et al. '544 patent. Even though the Greenspan '853 application does not specifically teach incorporating said bactericidal bioactive glass particles or composition into a cosmetic preparation, so as to preserve said preparation by imparting bactericidal protection against invading bacteria introduced by a consumer during usage of said preparation, motivation to do so exists, as the Greenspan '853 application explicitly teaches that the bactericidal bioactive glass particles and composition as disclosed therein are efficacious at imparting bactericidal protection against invading bacteria associated with the outer epithelial tissue layer of the skin. In addition, one of ordinary skill in the art would have had a reasonable expectation of success at preserving the perishable cosmetic preparation (as taught in the Shimono et al. '544 patent) by imparting (via the addition of the bactericidal bioactive glass particles or composition taught in the Greenspan '853 application) bactericidal protection against invading bacteria introduced into said preparation by the outer epithelial tissue layer of the skin of a consumer during usage of said preparation.

Claims 16-19 are rejected under 35 U.S.C. § 103(a) as being obvious in light of the combined teachings of the primary reference, namely the Shimono et al. '544 patent, in further view of the following secondary references, namely: Yamanaka et al., "Enzymatic Activity of Glucose Oxidase Encapsulated in Transparent Glass by the Sol-Gel Method," Chemistry of Materials, 4(3):495-497 (1992); Wu et al., "Bacteriorhodopsin Encapsulated in Transparent Sol-Gel Glass: A New Biomaterial," Chemistry of Materials, 5(1):115-120 (1993); and Wang et al., "Affinity of Antifluorescein Antibodies Encapsulated Within a Transparent Sol-Gel Glass," Analytical Chemistry, 65(19):2671-2675 (1993).

Claim 16 is directed, in part, to a bactericidal cosmetic preparation comprising a liquid carrier and an effective amount of bioactive glass particles so as to impart bactericidal properties to said preparation; wherein said bioactive glass particles have a refractive index sufficiently close to that of said liquid carrier so that said bioactive glass particles do not effectuate the appearance of said bactericidal cosmetic composition and are therefore substantially transparent to a consumer. Although the Shimono et al. '544 patent teaches a bactericidal cosmetic preparation comprising an effective amount of bioactive glass particles so as to impart bactericidal properties to said preparation, the Shimono et al. '544 patent fails to teach bioactive glass particles having a refractive index sufficiently close to that of a liquid carrier so that said bioactive glass particles do not effectuate the appearance of said bactericidal cosmetic composition are therefore substantially transparent to a consumer. However, the aforementioned secondary references, namely Yamanaka et al., 495 (1992), Wu et al., 115 (1993), and Wang et al., 2671 (1993), teach bioactive glass particles having a refractive index sufficient to impart a physical property of transparency to said bioactive glass particles. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of the Shimono et al. '544 patent with the combined teachings of secondary references, namely Yamanaka et al., 495 (1992), Wu et al., 115 (1993), and Wang et al., 2671

(1993), to produce a bactericidal cosmetic preparation comprising bioactive glass particles having a refractive index sufficiently close to that of a liquid carrier so as to impart an undetectable transparent, and therefore "invisible," physical property to said bioactive glass particles within said bactericidal cosmetic composition. A manufacturer of cosmetic preparations would immediately recognize the benefit of producing a bactericidal cosmetic composition that is more aesthetically pleasing in appearance to conscientious cosmetic consumers by making the bioactive glass particles, which are contained within said cosmetic composition, undetectable. As a result, motivation and economic incentive exists for a manufacturer of a bactericidal cosmetic preparation to modify the refractive index of the transparent bioactive glass particles (as taught by the secondary references of Yamanaka et al., 495 (1992), Wu et al., 115 (1993), and Wang et al., 2671 (1993)) contained therein, so as to match the refractive index of said liquid carrier, thereby maintaining the transparent nature of said bioactive glass particles and imparting an "invisible" and therefore undetectable physical property to said bioactive glass particles, which are present within said bactericidal cosmetic composition (as taught in the Shimono et al. '544 patent).

Claims 16 and 17 are collectively directed to a bactericidal cosmetic preparation comprising an effective amount of bioactive glass particles so as to impart bactericidal properties to said preparation; wherein said bioactive glass particles are present in an amount of: less than or equal to 10 % by weight of said preparation (claim 16); and said bioactive glass particles have a diameter of: less than or equal to 400 μm (claim 16); and a diameter of less than or equal to 10 μm or 5 μm (claim 17). Similarly, the Shimono et al. '544 patent also discloses a bactericidal cosmetic preparation comprising an effective amount of bioactive glass particles to said preparation to impart bactericidal properties to said preparation, wherein said bioactive glass particles are present in an amount of less than or equal to 2.5 % by weight of said preparation (column 1, lines 11-14 and 38-41; column 3, line 36; column 4, line 18; column 5, line 33; column 6, line 17; and

column 7, line 9) and said bioactive glass particles have a diameter of less than or equal to 600 μm with an average particle diameter of 20 μm or less, and a preferred particle diameter of less than or equal to 10 μm or 5 μm (abstract; column 2, lines 20-21 and 45-61; column 3, lines 46-47; column 4, lines 31-32; column 6, lines 32-33; column 7; lines 25-26; and claim 1).

Claim 18 is directed to a preparation according to claim 16, wherein said bioactive glass particles contain diphosphorous pentoxide (P_2O_5) in an amount greater than or equal to 2 % by weight of said bioactive glass particles. Similarly, the Shimono et al. '544 patent also discloses a bactericidal cosmetic preparation, wherein bioactive glass particles contain diphosphorous pentoxide (P_2O_5) in an amount of 50 mole % of said bioactive glass particles (column 4, line 27; column 6, line 28; and column 7, line 21).

Claim 19 is directed to a preparation according to claim 18, wherein said bioactive glass particles do not contain or release at least one toxic metal cation. Similarly, the Shimono et al. '544 patent also discloses a bactericidal cosmetic preparation, wherein bioactive glass particles do not contain or release at least one toxic metal cation selected from the group consisting of Ag^+, Cu^{2+}, Cu^+ and Zn^{2+}, in toxic concentrations when applied directly to the epithelial tissue of the skin (abstract; column 1, lines 6-10 and 46-53; column 2, lines 3-44; column 3, lines 3-11 and 36; column 4, line 18; column 5, line 33; column 6, line 17; column 7, line 9; and claim 1).

Remarks

Receipt of the Applicant's Response, to the Official Action dated July 14, 2004, which was filed on November 12, 2004, is acknowledged. Although the Applicant's arguments have been fully considered, they remain unpersuasive. Epithelial tissue not only covers all of the external parts of the body, but also lines the gastrointestinal tract including the mouth. Bioactive glass compositions that impart bactericidal properties on the epithelial tissue lining the mouth would likewise be reasonably expected to exhibit similar bactericidal

properties on the epithelial tissue covering the external parts of the body. This is especially the case when the epithelial tissue covering the external parts of the body is moist due to, for example: body fluids associated with a superficial wound; saliva associated with the lips; and perspiration associated with the face, underarms and feet. One of ordinary skill in the art of formulating cosmetic compositions to impart bactericidal properties against contamination of said composition by bacteria introduced into said composition via contact with bacteria associated with the surface of the epithelial tissue covering the external parts of the consumer's body during usage thereof would in fact search the scientific literature for agents that are known to exhibit bactericidal properties against bacteria-bearing epithelial tissue, whether said epithelial tissue is associated with the inner linings of the mouth or the external covering of the body. In addition, there is a plethora of readily available scientific literature on the internet and one of ordinary skill in the art of formulating bactericidal cosmetic compositions need not be well versed in the field of dentistry to locate scientific literature relevant to agents that impart bactericidal properties against bacteria associated with epithelial tissue.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David P. Stitzel, Esq. whose telephone number is 571-272-8508. The examiner can normally be reached on Monday-Friday, from 8:30AM-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached at 571-272-0887. The fax number for Group Art Unit 1616, which is where this application or proceeding is assigned, is 703-872-9306.

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